UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

KNOPP NEUROSCIENCES INC., Plaintiff, v. BIOGEN IDEC INTERNATIONAL HOLDING LTD, Defendant.	Civil Action No.:

COMPLAINT

Knopp Neurosciences Inc. ("Knopp"), by and through its attorneys, K&L Gates LLP, files the following Complaint, and in support thereof states the following:

NATURE OF THE ACTION

This is an action for Declaratory Relief, Specific Performance, and Preliminary and Permanent Injunctive Relief to preserve and protect whole blood and blood plasma materials ("biosamples") from nearly a thousand patients suffering from amyotrophic lateral sclerosis ("ALS"), pending this Court's determination whether defendant Biogen Idec International Holding Ltd. ("Biogen Idec") is required to transfer and assign these biosamples to Knopp under a license agreement that Biogen Idec has purported to terminate. ALS, also known as Lou Gehrig's disease, is a devastating and universally fatal neurodegenerative disorder. Failure to preserve the status quo as to these biosamples pending this determination will irreparably deprive Knopp and the ALS community of a priceless, unique, and irreplaceable resource for

fundamental and potentially life-altering research for the benefit of ALS patients and their families. This action also seeks a judgment of Biogen Idec's breach of that license agreement, and other relief for breach including damages and an order requiring Biogen to specifically perform all its obligations under the license agreement.

THE PARTIES

1. Plaintiff Knopp, a Delaware corporation with its principal place of business at 2100 Wharton Street, Suite 615, Pittsburgh, PA 15203, is a Pittsburgh-based biotech company that, along with its affiliated companies, is focused on treatments for ALS and other incurable diseases.

2. Defendant Biogen Idec, a company organized under the laws of Bermuda, has its principal place of business in Hamilton, Bermuda.

JURISDICTION AND VENUE

3. The amount in controversy exceeds $75,000. There is diversity of citizenship between Knopp and Biogen Idec. Jurisdiction is based upon 28 U.S.C. § 1332(a)(2).

4. A substantial part of the facts and circumstances out of which this Complaint arises occurred in the District of Massachusetts. Moreover, the license agreement between Knopp and Biogen Idec under which this action arises designates the state and federal courts sitting in Boston, Massachusetts, as the exclusive venue for any action. Venue is, therefore, proper in this Court pursuant to 28 U.S.C. § 1391(a).

FACTUAL BACKGROUND

A. THE LICENSE AGREEMENT

5. ALS is characterized by progressive paralysis and the inexorable loss of the ability to walk, talk, eat, and breathe. Most victims die within two to five years of diagnosis, often in the prime of life and usually with their cognitive function intact. Only a single drug, riluzole, which

increases survival by approximately two months without slowing the rate of paralysis, has been approved for the treatment of ALS. There have been no new drug approvals for patients with ALS since 1995.

6. On its own, Knopp advanced a drug candidate, KNS-760704, also known as "dexpramipexole" or "dex," through a Phase 2 clinical trial in 102 patients with ALS that showed dose-dependent benefits in slowing the rate of paralysis and reducing the risk of mortality in patients whose ALS was progressing rapidly.

7. To develop dexpramipexole through a Phase 3 clinical trial that might lead to its approval by the FDA for use in ALS, Knopp needed to raise additional capital.

8. Additional capital was available through private equity, the public markets, and partnership with a larger biopharmaceutical company.

9. Biogen Idec describes itself as the oldest independent biotechnology company in the world, with R&D efforts focused on bringing new therapies to market for patients with neurodegenerative diseases, autoimmune disorders and hemophilia.

10. In August 2010, after a year of intensive negotiations, Knopp exclusively licensed the global development and commercialization rights for dexpramipexole (the "Licensed Product") to Biogen Idec pursuant to a written license agreement ("License Agreement").

11. Pursuant to the License Agreement, Knopp transferred to Biogen Idec the Investigational New Drug application ("IND") for the development of dexpramipexole in ALS.

12. The holder of the IND is the party authorized by the U.S. Food and Drug Administration ("FDA") to conduct clinical trials of investigational drugs such as dexpramipexole.

13. The IND holder controls and conducts interactions with regulatory authorities and is responsible for maintaining records relating to the drug's development.

14. The License Agreement, however, limited Biogen Idec's rights with respect to the Licensed Product in a number of fundamental ways during the term of the License Agreement.

15. For example, the License Agreement defines "Discovery Research" as:

> any research activities with respect to KNS-760704 and/or any Licensed Product which relate to (a) its biological or biochemical effects in any *in vitro* or *in vivo* systems (but not including clinical effects in human subjects); (b) chemistry modifications of its structure for the purpose of developing a Next Generation Compound; (c) its use for developing targets or assays which may be useful for the purpose of developing a Next Generation Compound; or (d) any attempt to characterize or identify the mechanism of action or molecular site of action of KNS-760704 and/or any Licensed Product or any attempt to identify, create or characterize one or more Next Generation Compounds. For purposes of illustration and without limiting the term in any manner, the term "Discovery Research" includes the use of *in vitro* preparations to characterize or identify the mechanism of action or molecular site of action of KNS-760704 and/or any Licensed Product, using KNS-760704 and/or any Licensed Product to develop screens which may be useful for the purpose of developing a Next Generation Compound, and using KNS-760704 and/or the Licensed Product in *in vivo* animal models of diseases in which the Licensed Product may exert a beneficial effect.

16. From the beginning of the negotiation, Knopp made it clear that the right to conduct Discovery Research was not part of the deal. On this point, Knopp never wavered, and Biogen Idec accepted this limitation in Section 2.2(b) of the License Agreement, which provides, in pertinent part, "for the avoidance of doubt, the license grant in Section 2.1 does not include the right by Biogen Idec, its Affiliates, or Third Party Sublicensees to conduct any Discovery Research."

17. The express exclusion of Discovery Research from Biogen Idec's license grant in Section 2.2(b) is reinforced in a number of provisions of the License Agreement.

18. For example, the definition of "Development Research" itself provides: " . . . the term 'Development Research' specifically excludes the use of KNS-760704 and/or any Licensed

Product in any type of Discovery Research, in whole or part." Likewise, the definition of "Develop" and "Development" states, "[f]or avoidance of doubt, "Development" does not include Discovery Research."

19. The License Agreement recognizes that the actual allocation of intellectual property rights agreed to by the parties as expressed in the broad definition of "Discovery Research" might lead to a situation in which a regulatory authority requires Biogen Idec to do what is plainly "Discovery Research" on dexpramipexole forbidden to it under the License Agreement.

20. Consequently, subsections (i) through (v) of Section 2.2(b) of the License Agreement provide that such required Discovery Research may be performed, but only with Knopp doing the work or Knopp agreeing to permit Biogen Idec or others to do the work, and the parties then treating the intellectual property resulting from all such research as prescribed in those subsections.

21. The post-termination provisions of the License Agreement were designed to return control of dexpramipexole entirely to Knopp and to enable Knopp to benefit from and build upon Biogen Idec's research and development efforts during the time the license was in effect.

22. For example, upon termination of the License Agreement, all of Biogen Idec's rights in the Licensed Product terminate, and Biogen Idec is required to, among other things, "promptly transfer and assign to Knopp all Regulatory Documentation and other technical and other information or materials in Biogen Idec's or its Affiliates' possession or control relating to the Licensed Product, anywhere in the world." License Agreement, Section 15.3(b)(v).

23. Moreover, unless Biogen Idec terminates the License Agreement on account of Knopp's insolvency or bankruptcy pursuant to Section 15.2(b) or for "material safety concerns" or "futility" as defined in Section 15.2(d), upon termination Biogen Idec is obligated "to pay the

direct out-of-pocket costs and the FTE [full time employee] Costs that are actually and reasonably incurred by Knopp to continue for a period of ten (10) months from the date of termination in conducting both the Biogen Idec and Knopp obligations under the Development Plan and Commercialization Plan (including all Clinical Trials and Commercialization that are on-going at the time of termination), and the on-going activities, including, if applicable, Clinical Trials and related Regulatory Approvals of the Licensed Products will be transitioned to Knopp or its designee(s) . . ." License Agreement, Section 15.3(b)(viii).

B. MODERN BIOMEDICAL RESEARCH, BIOSAMPLES, AND BIOMARKERS

24. The quest for breakthrough treatments for complex diseases such as ALS includes molecular research at three primary levels: genomics, proteomics, and metabolomics.

25. Genomics involves the study of unique, inherited DNA sequences in individuals, as well as common DNA patterns across groups, such as a particular species or a subpopulation of humans.

26. Of particular interest to Knopp and other pharmaceutical companies is the practice of pharmacogenomics, which seeks to identify inherited DNA signatures that predict the effectiveness of a drug, and its potential for side effects, in a particular individual or subpopulation.

27. Proteomics involves the study of proteins within an individual or group. Proteins are not only the structural building blocks of life, they act as molecular messengers and biochemical catalysts that maintain health and become dysfunctional in disease.

28. Metabolomics refers to the study of molecules created by metabolic processes within the body, chiefly through the creation and consumption of cellular energy resources.

29. The association of these biochemical signatures with disease progression and drug treatment signals a promising new era of pharmaceutical research.

30. Spanning the fields of genomics, proteomics, and metabolomics is an additional research objective critical to progress in ALS: the development of disease biomarkers.

31. Biomarkers are quantitative measurements of specific molecules that correlate with disease severity, disease progression, drug action, response to treatment, or combinations thereof. A well-known example is the level of LDL cholesterol as both a surrogate for cardiovascular health and as a test of responsiveness to treatment with drugs in the statin, or cholesterol-lowering, class.

32. Biosamples are the materials necessary to investigate biomarkers.

33. To remain viable for research, biosamples must be stored in frigid conditions, typically at a temperature of -80 degrees Celsius (-120 degrees Fahrenheit), and maintained through rigorous monitoring and quality control.

34. The loss of samples due to inadequate control can be a tragic and irrecoverable event in biomedical research.

C. EMPOWER AND ITS AFTERMATH

35. As the holder of the IND pursuant to the License Agreement, Biogen Idec initiated a large, global Phase 3 trial of the drug in 943 ALS patients that lasted for approximately eighteen months. This clinical trial was branded by Biogen Idec as the EMPOWER study ("EMPOWER").

36. As part of EMPOWER, Biogen Idec collected biosamples from ALS patients at multiple intervals both to assess the potential side effects of the drug and to hold for future research purposes ("EMPOWER biosamples").

37. In the summer of 2011, Biogen Idec proposed using the EMPOWER biosamples to perform biomarker studies.

38. Biogen Idec and Knopp disagreed as to whether the proposed biomarker studies would constitute Discovery Research or Development Research under the License Agreement.

39. Consequently, on August 11, 2011 they entered into a letter agreement ("Biomarker Studies Agreement") governing the proposed biomarker studies.

40. The Biomarker Studies Agreement permitted Biogen Idec to collect blood samples from ALS patients, including those who had received dexpramipexole, but limited any analysis of the whole blood, serum, and plasma from these samples for ALS-related biomarkers "both: (i) solely with respect to subjects who have not received KNS-760704 or Licensed Product and (ii) without any use of KNS-760704 or any Licensed Product (collectively 'Current Activities')."

41. The Biomarkers Study Agreement further required Biogen Idec to give Knopp at least ninety (90) days' written notice and to provide Knopp with specified information prior to the proposed commencement of any biomarker studies that involve the analysis of biosamples from subjects who have received KNS-760704 ("Dex Biomarker Studies").

42. The Biomarkers Studies Agreement then required that Knopp and Biogen Idec meet to discuss whether the proposed Dex Biomarker Studies constitute Discovery Research or Development Research under the License Agreement.

43. In the Biomarkers Studies Agreement, both parties preserved their legal positions as to whether biomarkers studies generally or Dex Biomarker Studies are Discovery Research or Development Research, with any disputes to be ultimately resolved in accordance with the arbitration provisions of the License Agreement.

44. Biogen Idec's dissatisfaction with the limitations on Discovery Research it had agreed to in the License Agreement and its eagerness to perform Dex Biomarker Studies continued to cause friction as EMPOWER continued.

45. Biogen Idec and Knopp held a "biomarkers summit" in October, 2011, and started working on a supplemental biomarkers studies agreement to address proposed Dex Biomarker Studies.

46. Although these discussions were continuing, at the end of May 2012, Biogen Idec informed Knopp that it was unilaterally commencing certain biomarker studies based on its determination that these studies were Development Research, not Discovery Research.

47. Prior to this announcement, Biogen Idec had not provided the ninety-day notice required by the Dex Biomarker Studies Agreement or fully engaged in the discussions or dispute resolution proceedings required under the Biomarker Studies Agreement.

48. Despite further exchanges on this subject, no real progress was made on resolving this dispute as the time for the "top line" results of the EMPOWER study approached.

49. On January 3, 2013, Biogen Idec announced the results of EMPOWER, which showed that dexpramipexole was generally safe and well tolerated but failed to meet its pre-specified primary and secondary endpoints, and furthermore failed to show any treatment benefit in selected subgroups within the trial that were analyzed by Biogen Idec.

50. As a result, Biogen Idec announced the immediate suspension of further development of the drug for ALS patients.

51. Shortly after announcing the EMPOWER results, representatives of Biogen Idec contacted their counterparts at Knopp to begin making arrangements to transfer the IND, data,

information, and other materials relating to dexpramipexole to Knopp as required by the License Agreement.

52. Thereafter, by letter dated January 17, 2013 ("Termination Letter"), Biogen Idec formally notified Knopp that Biogen Idec had decided to discontinue development of dexpramipexole and was terminating the License Agreement, effective in sixty days.

53. The Termination Letter did not cite any provision of the License Agreement that permitted Biogen Idec to terminate following the EMPOWER study.

54. It did, however, state that Biogen Idec looked forward "to working with your team over the next couple of weeks to discuss next steps in winding down Biogen Idec's dexpramipexole program and finalize transition plans."

55. Biogen Idec's Termination Letter does not specify the basis of its claimed right to terminate the License Agreement, but the purported termination is likely subject to arbitration pursuant to Section 16.2 of the License Agreement.

56. Knopp reserves its right to contest Biogen Idec's termination of the License Agreement in arbitration pursuant to Section 16.2 of the License Agreement.

57. Knopp's independent analysis of the EMPOWER data revealed subgroups of the total study population that exhibited slower disease progression and reduced mortality when treated with dexpramipexole.

58. The treatment effects observed within the subgroups were clinically important and in multiple analyses approached or exceeded tests of statistical significance, but had not been identified by Biogen Idec.

59. At a Joint Steering Committee ("JSC") meeting held on Wednesday February 13, 2013, Knopp presented its analysis of the EMPOWER data to Biogen Idec.

60. On Thursday, February 14, 2013, Knopp was informed that Biogen Idec's statisticians had confirmed the accuracy of Knopp's analysis of the EMPOWER data.

61. In light of its analysis of the EMPOWER results, Knopp's current activities remain focused on advancing dexpramipexole as a potential treatment for ALS patients, especially those patients with the most rapidly progressing form of the disease.

62. Knopp's larger mission includes investigating the pathophysiology of ALS and discovering additional treatments for the disease.

63. The EMPOWER biosamples sit squarely within each of these objectives and are among the most important materials Biogen Idec was obligated to "transfer and assign" to Knopp under the terms of the License Agreement.

64. The search for effective treatments for ALS remains hampered by the absence of a validated biomarker of disease progression or response to treatment.

65. This missing link has led to unproductive trial and error in selecting drugs for clinical development, in establishing enrollment criteria, in choosing dose levels for testing, and in setting the parameters for testing drug effects.

66. At least 20 consecutive drug candidates for ALS have failed in large clinical trials over the past 18 years. The lack of an ALS biomarker impaired the EMPOWER study itself.

67. The EMPOWER biosamples represent a priceless, unique, and irreplaceable resource to conduct genomic, proteomic, metabolomic, and biomarker research, both for the future development of dexpramipexole by Knopp and for the ALS research community at large.

68. While biosamples are regularly collected within the ALS research community, most of these are acquired on a sporadic basis to fulfill limited research objectives.

69. By contrast, biosamples collected as part of a large, long-term drug trial such as EMPOWER possess tremendous research value.

70. Each EMPOWER patient from whom samples were taken was extensively evaluated in the clinic over regular intervals for up to a year and a half.

71. This means the molecular information harbored in any patient's biosamples can be tightly correlated with the same patient's death or survival, rate and nature of disease progression, use of other medications, vital signs, blood chemistry and immune status, other health conditions, and quality of life, to say nothing of the patient's age, gender, race, country of residence, and other demographic characteristics.

72. While molecular data and clinical data are valuable separately, neither can approach the synergistic value of acquiring those data sets from the same subjects at the same time and analyzing them in combination.

73. Inherent in this opportunity is the equal division of EMPOWER subjects between those treated with dexpramipexole and those who received placebo.

74. The research techniques enumerated above may be applied both to the treated and untreated subjects in the study for differential analysis of the effects of the drug and its potential to alter the natural history of the disease.

75. Future clinical trials of dexpramipexole would benefit from these differential analyses.

76. An advantage of the EMPOWER biosamples in their own right is their collection within a highly controlled, experimental setting under a single research protocol.

77. The EMPOWER biosamples were also collected according to an informed consent protocol that permits their use for biomedical research, including DNA analysis.

78. This means these materials have been secured from patients, prepared for storage, and placed in holding under the same conditions, regardless of time or geography. Research objectives are routinely frustrated when all materials are not collected under the identical protocol and hence under identical conditions. This is especially true in proteomics research, because proteins are highly unstable molecules whose structures and activity are significantly influenced by the conditions under which they are collected and handled for storage.

79. Before it decided to abandon the development of dexpramipexole for the treatment of ALS, Biogen Idec itself emphasized the critical importance of performing genetic analysis of the EMPOWER participants' biosamples, at one point declaring that "[We] may well find that dex is a poster child for this type of drug development."

80. The EMPOWER biosamples are also irreplaceable because they are available today.

81. In the pipeline of ALS drug candidates, Knopp is not aware of any program anywhere in the world that will reach an extent of clinical testing equivalent to EMPOWER within at least the next two years.

82. Moreover, most current investigational drugs for ALS are years away from Phase 3 testing, if they ever reach that stage at all.

83. The failure to preserve the EMPOWER biosamples, and ultimately to investigate them using the right tools in the right hands, will represent a research setback during which time thousands of patients will have died of ALS.

84. While Biogen Idec has given up on dexpramipexole for ALS, Knopp has not; consequently protecting the EMPOWER biosamples pending determination of who is entitled to them is of paramount concern to Knopp's ongoing dexpramipexole development program, to Knopp's larger ALS research objectives, and, ultimately, to ALS patients and their families.

85. Given Biogen Idec's announced intention to abandon development of dexpramipexole, Knopp was concerned that Biogen Idec might not appropriately recognize or appreciate the extraordinary importance of the EMPOWER biosamples to continuing ALS research or acknowledge the potential for the EMPOWER biosamples to accelerate the development of dexpramipexole and to increase the likelihood that dexpramipexole might be delivered to those patients most likely to benefit from it.

86. Knopp's concern was heightened when Biogen Idec provided Knopp with a PowerPoint slide deck describing wind down activities that made no mention whatsoever of the EMPOWER biosamples.

87. After seeing the slide deck, Michael E. Bozik, M.D., Knopp's President and CEO, sent Amit Rakhit, M.D., VP of Program Leadership and Management at Biogen Idec an email concerning the EMPOWER biosamples on January 25, 2013.

88. Dr. Rakhit had led the dexpramipexole development program at Biogen Idec, and had been designated as Biogen Idec's point person for the wind down activities.

89. Dr. Bozik's email read in its entirety as follows:

> Amit,
>
> Mary forwarded to me the slide deck she received from Bina yesterday of Biogen Idec's "Dexpramipexole Wind Down Plans" (attached). On initial review, I was struck that Bina's slide deck makes no mention of the biosamples taken from EMPOWER participants and especially that these biosamples are omitted from those slides listing the items that Biogen Idec plans to deliver to Knopp in connection with the transfer of the IND and other wind down activities. These biosamples are irreplaceable and invaluable. Therefore, please confirm that the biosamples are being properly maintained and preserved and will be provided to Knopp along with all other materials relating to the IND and the Licensed Product when the License Agreement terminates. In the meantime, of course, Biogen Idec and/or its agents/contractors should not be accessing or using the biosamples for any purpose.

> Knopp has several other questions and concerns about Biogen Idec's termination letter and the slide deck, but none as immediately urgent as protecting the integrity of the biosamples, which is why I'm raising this issue now. Knopp will follow up with Biogen Idec on these other matters shortly. In the meantime, I look forward to hearing from you about this important matter right away.
>
> Mike

90. In a follow-up phone call with Dr. Rakhit that same day, Dr. Bozik reiterated Knopp's concern that Biogen Idec preserve and protect the EMPOWER biosamples until they could be transferred to Knopp.

91. Dr. Rakhit responded that he did not know where the EMPOWER biosamples were being stored and that because Biogen Idec was terminating the development of dexpramipexole, he was not even certain that Biogen Idec had any further plans for the EMPOWER biosamples.

92. In a follow-up call four days later, Dr. Rakhit told Dr. Bozik that he did not believe that the terms of the informed consent forms ("ICF") that Biogen Idec had used to obtain the EMPOWER biosamples permitted Biogen Idec to transfer the EMPOWER biosamples to Knopp.

93. Dr. Rakhit's responses further increased Knopp's alarm concerning the fate of the EMPOWER biosamples pending an agreement or judicial determination as to who is entitled to them under the terms of the License Agreement.

94. Consequently, Knopp sought specific assurances that Biogen Idec would preserve and protect the integrity of the EMPOWER biosamples pending a determination as to who was entitled to them.

95. The only assurance that Biogen Idec would provide at that time was that Biogen Idec had made no decision to discard the EMPOWER biosamples.

96. Biogen Idec refused to disclose how and where the EMPOWER biosamples were being maintained.

97. In addition to relying on the language of the ICFs it had used in connection with the collection of the EMPOWER biosamples, Biogen Idec also subsequently claimed the License Agreement was silent as to whether Biogen Idec was required to transfer the EMPOWER biosamples to Knopp.

98. Knopp addressed Biogen Idec's refusal to comply with the License Agreement in its January 31, 2013 letter responding to Biogen Idec's Termination Letter.

99. Knopp's letter read in pertinent part as follows:

> Biogen Idec has told us that, at least with respect to the genetic analysis samples, the language of the informed consent form used to obtain those samples prohibits transfer to a third party. In addition, Biogen Idec maintains that it is not contractually obligated to transfer biosamples to Knopp following termination of the license agreement.
>
> Knopp disagrees with your conclusion. Under section 15.3(b)(v) of the License Agreement, those biosamples become the property of Knopp upon contract termination. Furthermore, IND #75,959 will be transferred to Knopp, along with all obligations attendant thereto. Knopp disagrees that the ICF prohibits transfer of the biosamples to Knopp. Moreover, Biogen Idec's perceived prohibition against transferring the samples to Knopp does not relieve it of its requirement to perform its contractual obligations. Knopp insists that Biogen Idec comply with those obligations to provide the samples to Knopp.
>
> In this regard, please immediately provide the previously requested information about the number, type, location, storage conditions and integrity of all biosamples secured under the dex program, and please confirm that none of them has been promised or provided to third parties (other than contractors who are merely storing them), and please confirm that none of them have been analyzed, studied or otherwise exploited or consumed by Biogen Idec. As I highlighted for you in my email last Friday, we are particularly concerned that Biogen Idec, or anyone acting on its behalf, maintains, protects, and preserves the biosamples pending orderly

> transfer to Knopp. This means that Biogen Idec, and anyone acting on its behalf, must not perform any analysis or studies with respect to these biosamples, or seek to otherwise use or exploit them for any purpose.
>
> The biosamples are unique, irreplaceable, and essential to Knopp's assessment of the EMPOWER results. Please provide me, no later than close of business Monday, February 4, 2013, with answers to my questions above as well as specific, verifiable assurances that Biogen Idec and anyone acting on its behalf are maintaining the integrity of the biosamples and are not seeking to study or exploit them in any way pending their transfer to Knopp. It is critical to the future of both dex and Knopp that Knopp's rights to these biosamples be fully preserved and protected. The harm resulting from any failure to so preserve them would be irreparable.

100. Biogen Idec ignored Knopp's request that it provide assurances as to maintaining the *status quo* with respect to the biosamples by February 4, 2013.

101. Instead, the next day, February 5, Dr. Rakhit sent Dr. Bozik an email stating:

> Specifically as to the biosamples, we (Biogen Idec) do not believe we have an obligation to deliver the biosamples or the related details you requested given the language provided in the patient informed consent forms as well as our interpretation of the language in the License Agreement.

102. After a number of follow up exchanges, on February 11, 2013, Biogen Idec's in-house counsel confirmed that Biogen Idec was maintaining its position that it is not allowed or required to transfer the EMPOWER biosamples to Knopp and that it would not even provide Knopp the information Knopp had requested concerning the number, type, location, storage conditions, and integrity of all the EMPOWER biosamples.

103. The only assurance Biogen Idec would provide was that it was not "currently" conducting research on the EMPOWER biosamples and would abide by the restrictions of the License Agreement as Biogen Idec interpreted them.

104. At the February 13, 2013 JSC meeting to discuss wind-down and other issues relating to Biogen Idec's purported termination of the License Agreement, Knopp again raised the issue of protecting the EMPOWER biosamples.

105. Dr. Rakhit repeated that Biogen Idec was not currently using the EMPOWER biosamples and acknowledged that Knopp's presentation of the EMPOWER data provided additional context with respect to the requests Knopp had made during the JSC meeting.

106. Following the JSC meeting, Knopp's counsel promptly followed up with Biogen Idec's counsel in an email and suggested another phone call in an attempt to resolve the dispute.

107. Biogen Idec's counsel responded that "I'll talk with [Dr. Rakhit] tomorrow to get the download re the biosamples and Knopp's presentation and then I'll get back to you with a time."

108. The follow up phone call took place on February 18th. It was brief.

109. While acknowledging that Biogen Idec understood why the EMPOWER biosamples are important to Knopp, Biogen Idec's counsel stated that Biogen Idec's position was unchanged (i.e., that it had no obligation to transfer and assign the EMPOWER biosamples and that it would not identify the number, type, location, storage conditions, and integrity of all the EMPOWER biosamples, or provide any assurances that Biogen Idec would not use them itself pending resolution of the dispute over Biogen Idec's obligation to transfer and assign them to Knopp under the terms of the License Agreement).

110. Knopp's counsel responded that Biogen Idec would be hearing back from Knopp about this matter shortly.

111. That same day Knopp sent Biogen Idec a letter reiterating Biogen Idec's obligation to transfer and assign the EMPOWER biosamples to Knopp under the terms of the License Agreement and demanding that Biogen Idec provide assurances that it would do nothing to

threaten the integrity or availability of the EMPOWER biosamples pending resolution of the dispute as to the entitlement to the EMPOWER biosamples.

112. Knopp's letter stated that if assurances as to the maintenance of the status quo of the EMPOWER biosamples were not provided by February 21, 2013, Knopp would have no choice but to initiate an action seeking a determination of its rights to the EMPOWER biosamples under the License Agreement, including a request for a preliminary and permanent injunction protecting the EMPOWER biosamples pending judicial resolution of Knopp's request for a declaratory judgment and order of specific performance with respect to the transfer of the EMPOWER biosamples.

113. Rather than provide the requested assurances, in the afternoon of February 21, 2013, Biogen Idec sent Knopp a letter rejecting any obligation to transfer and assign the EMPOWER biosamples to Knopp.

114. With respect to Knopp's request for assurances as to the preservation of the EMPOWER biosamples, Biogen Idec stated that it "is following its standard procedures to assure the integrity of the biosamples . . . and it is working to develop plans for a number of research projects using the EMPOWER biosamples for the ultimate benefit of the ALS community."

115. Given Biogen Idec's disregard of its obligations to transfer and assign the EMPOWER biosamples to Knopp and its announced intent to use the EMPOWER biosamples itself, Knopp was left with no choice but to bring this action.

COUNT I – BREACH OF CONTRACT

116. Knopp hereby incorporates the allegations of paragraphs 1 through 115 as if fully set forth in this Count.

117. As noted above, even during the term of the License Agreement, Biogen Idec's rights were specifically limited in certain material respects.

118. In particular, as explained above, Biogen Idec was not permitted to perform Discovery Research, as defined in the License Agreement.

119. Although it is impossible to make a definitive determination at this point because of Biogen Idec's failure to set forth the basis for its termination of the License Agreement, issues with respect to the validity of Biogen Idec's termination of the License Agreement are likely subject to arbitration under Section 16.2 of the License Agreement.

120. Section 15.3 of the License Agreement also sets forth detailed, extensive provisions governing the effect of termination of Biogen Idec's license.

121. The essential intent of these termination provisions is two-fold: The first is to rescind the license granted to Biogen Idec in connection with the development of dexpramipexole for ALS; the second is to facilitate Knopp's ability to continue to pursue the development and commercialization of dexpramipexole in ALS after Biogen Idec abandons its rights under the License Agreement.

122. Indeed, nearly all of the provisions of Section 15.3(b) are designed to place Knopp in the most advantageous position possible to carry on dexpramipexole development and research for the potential benefit of patients with ALS.

123. For example, Section 15.3(b)(i) requires Biogen Idec to provide Knopp "a materially accurate, reasonably detailed written description of the status of the Development and Commercialization of the Licensed Product through the effective date of termination within sixty (60) days of such termination."

124. Under Section 15.3(b)(ii), Biogen Idec grants Knopp a post-termination "non-exclusive, worldwide, perpetual (subject to termination for breach), royalty-free, assignable license, with the right to grant sublicenses, under the Biogen Idec Licensed Product IP . . . to (A) conduct or have conducted Discovery Research relating solely to KNS-760704 and Licensed Products (including Combination Products), (B) Exploit Licensed Products. . ."

125. Under Section 15.3(b)(iv), "[i]f applicable, Biogen Idec shall, subject to any obligations to or rights of Biogen Idec's or its Affiliates' Commercial Sublicensees, promptly transfer and assign to Knopp all of Biogen Idec's and Biogen Idec's Affiliates' rights, title and interests in and to the Licensed Product Trademarks, as well as all Promotional Materials and Educational Materials."

126. Under Section 15.3(b)(v), as previously noted, "Biogen Idec shall promptly transfer and assign to Knopp all Regulatory Documentation and other technical and other information or materials in Biogen Idec's or its Affiliates' possession or control relating to the Licensed Product, anywhere in the world."

127. Under Sections 15.3(b)(vi), and 15.3(d)(iv), (v) and (vi), all intellectual property and patent rights are assigned to Knopp.

128. Finally, as noted above, under Section 15.3(b)(viii), unless Biogen Idec terminates the License Agreement on account of Knopp's insolvency or bankruptcy (Section 15.2(b) or for "material safety concerns" or "futility" as defined in Section 15.2(d) of the License Agreement (none of which Biogen Idec has alleged), Biogen Idec is obligated "to pay the direct out-of-pocket costs and the FTE Costs that are actually and reasonably incurred by Knopp to continue for a period of ten (10) months from the date of termination in conducting both the Biogen Idec and Knopp obligations under the Development Plan and Commercialization Plan (including all

Clinical Trials and Commercialization that are on-going at the time of termination), and the on-going activities, including, if applicable, Clinical Trials and related Regulatory Approvals of the Licensed Products will be transitioned to Knopp or its designee(s) . . .."

129. On the face of the language in Section 15.3(b)(v) obligating Biogen Idec to "promptly transfer and assign to Knopp "all Regulatory Documentation and other technical information and other information or materials" necessarily includes biosamples.

130. "Regulatory Documentation" is itself a broadly defined term under Section 1.158 of the License Agreement:

> "Regulatory Documentation" means all IND applications, NDAs, MAAs or foreign equivalents thereof submitted to any Regulatory Authority, Regulatory Approvals, pre-clinical and clinical data and information, regulatory materials, drug dossiers, master files (including DMFs), regulatory designations such as orphan drug status and fast track designation, and any other reports, records, regulatory correspondence relating to Regulatory Approval of the Licensed Product (or Excluded Combination Product, as provided in Section 2.2(a)), including any information that relates to pharmacology, toxicology, chemistry, manufacturing and controls data, batch records, safety and efficacy, and any safety database.

131. The EMPOWER biosamples are "materials" that are related to "Regulatory Documentation," and would necessarily follow the IND holder, which is undisputedly going to be Knopp upon termination of the License Agreement.

132. From a regulatory perspective, the FDA would expect Knopp, as the IND holder, to have access to and control of the EMPOWER biosamples.

133. The use of the term "other … materials" sets forth the intent of Section 15.3(b)(v) to broadly sweep in everything generated or obtained by Biogen Idec in the course of development activities under the License Agreement, including biosamples that one would normally associate with an ongoing drug development program.

134. Moreover, blood samples are often referred to as "materials" and described under the "Materials and Methods" sections of biomedical research publications. Biogen Idec itself uses the term "materials" in connection with biological materials in all manner of legal documents—patent applications, confidentiality agreements, and contracts.

135. Additionally, legal agreements governing the use of biosamples by third party collaborators are typically captioned as "Material Transfer Agreements."

136. EMPOWER was not a generic ALS study, it was a study pursuant to the License Agreement in pursuit of the development of dexpramipexole for the treatment of ALS.

137. From a larger perspective, permitting Biogen Idec to retain the EMPOWER biosamples after termination of the License Agreement is inconsistent with the fundamental structure of the License Agreement.

138. In particular, considering the critical, irreplaceable importance of the EMPOWER biosamples to Knopp's continuing research and development efforts for dexpramipexole in ALS, allowing Biogen Idec to retain the EMPOWER biosamples would frustrate the parties' plain intent to facilitate Knopp's continuing research and development efforts once the License Agreement terminates.

139. For all these reasons, Biogen Idec's refusal to transfer and assign the EMPOWER biosamples to Knopp is a material breach of the agreement.

140. Section 15.3(d)(vii) of the License Agreement provides that termination of the License "Agreement shall be in addition to, and shall not prejudice, the Parties' remedies at law or in equity, including the Parties' ability to receive legal damages and/or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination."

141. Knopp has repeatedly informed Biogen Idec that Knopp expects the EMPOWER biosamples to be transferred and assigned to Knopp as part of the License Agreement wind-down activities, but Biogen Idec has repeatedly repudiated that obligation.

142. Knopp has also repeatedly requested that Biogen Idec provide assurances that it will preserve, protect, and maintain the integrity of the EMPOWER biosamples pending resolution of the dispute over Biogen Idec's obligation to transfer and assign the EMPOWER biosamples to Knopp under the terms of the License Agreement.

143. Biogen Idec has adamantly refused to provide the requested assurances, beyond stating that it is not "currently" exploiting them and will generally honor what it sees as its post-License Agreement termination obligations.

144. Knopp has met all the requirements for a preliminary injunction preserving the status quo as to the EMPOWER biosamples pending determination of Biogen Idec's obligation to transfer and assign the EMPOWER biosamples upon termination of the License Agreement.

145. First, Knopp is likely to succeed on the merits of its claim that Biogen Idec has breached the License Agreement by refusing to transfer and assign the EMPOWER biosamples to Knopp.

146. Second, the EMPOWER biosamples are unique, invaluable, and irreplaceable. Failure to preserve and protect them pending their transfer to Knopp will cause immediate and irreparable harm to Knopp and to ALS patients and their families.

147. Third, a preliminary injunction requiring Biogen Idec to preserve and protect the EMPOWER biosamples pending a final determination as to Biogen Idec's obligation to transfer and assign them to Knopp will cause no harm to Biogen Idec, while failing to enter a preliminary injunction preserving the status quo with respect to the EMPOWER biosamples could cripple Knopp's continuing efforts to investigate and develop dexpramipexole for treatment of ALS.

148. Fourth and finally, because failure to preserve the EMPOWER biosamples will deprive ALS suffers of potential life-altering treatments, preserving and protecting the EMPOWER biosamples pending a final determination as to Biogen Idec's obligation to transfer and assign them to Knopp overwhelmingly serves the public interest in improved treatment for ALS.

WHEREFORE, Knopp respectfully requests the following relief:

(a) a preliminary injunction:

(i) requiring Biogen Idec (and its agents/contractors) to preserve, protect, and maintain the integrity of the EMPOWER biosamples;

(ii) forbidding Biogen Idec (and its agents/contractors) from seeking to study or exploit the EMPOWER biosamples in any way pending determination as to whether Biogen Idec is obligated to transfer and assign the EMPOWER biosamples to Knopp; and

(iii) requiring Biogen Idec to file with the Court and serve on Knopp within three (3) days of the date of the preliminary injunction a detailed report as to the type, number, location, storage conditions, and integrity of all the EMPOWER biosamples, including all processes and safeguards that Biogen Idec and/or its agents/contractors have put into place to preserve and protect the EMPOWER biosamples;

(b) a declaration that nothing in this action shall be deemed to waive or otherwise prejudice Knopp's rights to commence or pursue arbitration of any issues within the scope of Section 16.2 of the License Agreement, including issues relating to the validity or consequences of Biogen Idec's purported termination of the License Agreement;

(c) a declaration that Biogen Idec is obligated to promptly transfer and assign the EMPOWER biosamples to Knopp along with all other Regulatory Documentation, data, technical information and other materials relating to KNS-760704 (dexpramipexole) or the Licensed Product upon termination of the License Agreement;

(d) an order requiring Biogen Idec to specifically perform its obligation to promptly transfer and assign the EMPOWER biosamples along with all other Regulatory Documentation, data, technical information and other materials relating to KNS-760704 (dexpramipexole) or the Licensed Product;

(e) a judgment and declaration that, in addition to EMPOWER biosamples and Regulatory Documentation, Biogen Idec is obligated to transfer and assign any other materials, documentation, and rights as required under the License

Agreement, including but not limited to drug product, active pharmaceutical ingredient (API), Licensed Product Trademarks, Promotional Materials, and Educational Materials;

(f) to the extent Biogen Idec has failed to protect and preserve the EMPOWER biosamples or has otherwise studied, used, or exploited them prior to the entry of the preliminary injunction, damages in an amount to be determined at the trial of this matter;

(g) such other and further relief as the Court may deem just and proper.

Dated: February 25, 2012

Respectfully submitted,

/s/ John J. Cotter

_____

John J. Cotter (BBO # 554524)
K&L GATES LLP
State Street Financial Center
One Lincoln Street
Boston, Massachusetts 02111-2950
(617) 261-3100
John.Cotter@klgates.com

Joseph Leibowicz, Esquire
Pa. ID #64365
K&L Gates LLP
K&L Gates Center
210 Sixth Avenue
Pittsburgh, PA 15222
(412) 355-6500 (tel)
(412) 355-6501 (fax)
e: joseph.leibowicz@klgates.com
(*admission pro hac vice pending*)

Counsel for Plaintiff Knopp Neurosciences, Inc,

CERTIFICATE OF SERVICE

I hereby certify that the foregoing Complaint was served on February 25, 2013, upon all counsel of record via the Court's electronic filing system and upon all others unable to receive electronic service, via overnight courier delivery.

/s/ *John J. Cotter*

John J. Cotter (BBO # 554524)